



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,985	08/14/2001	James K. Mainquist	P0013US10	3858

29490 7590 07/20/2005

GENOMICS INSTITUTE OF THE
NOVARTIS RESEARCH FOUNDATION
10675 JOHN JAY HOPKINS DRIVE, SUITE E225
SAN DIEGO, CA 92121-1127

EXAMINER

SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
----------	--------------

1743

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,985

Applicant(s)

MAINQUIST ET AL.

Examiner

Arlen Soderquist

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-24, 27-35 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-24, 27-35 and 37-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9-10-04, 10-12-04</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1743

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 5, 2005 has been entered.
2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the curved surface of claim 7 and the additional component for performing high throughput assays or reactions in microtiter plates of claims 29-34 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. Claims 4-5 and 38 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 5 and 38 are directed to features of an element, the microtiter plate, that is not positively recited as part of the device being claimed. Therefore these claims fail to further limit the claims from which they depend.

Art Unit: 1743

4. Claims 1-13, 21-24 and 27-31 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the support, any structure thereon or additional structure required for the microtiter plate to be precisely positioned on the support and any cooperative structural connections required therefore (the structure and cooperative relationships required to define the position and place the microtiter plate thereat). The claims fail to positively require the presence of a support or provide any structural relationship between the support and the elements that define the position of the microtiter plate thereon. Additionally it appears that at least two or more elements are required for the precise positioning of a microtiter plate. For example in the instant case at least 2 alignment members configured to contact two walls of the microtiter plate and two pushers are required to position the microtiter plate at a precisely defined position of the support that appears to be defined by the two members. Additionally the structural connections between the various alignment members, pushers and support are not clearly defined. Also the elements that define the position on the support that it is desired to place the microtiter plate are not set forth. For example in the instant case at least 2 alignment members configured to contact two walls of the microtiter plate and two pushers are required to position the microtiter plate at a precisely defined position of the support that appears to be defined by the two alignment members.

5. Claims 14-24 and 27-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 14, it is not clear how the lip surface can be recessed from itself. Additionally, it is not clear what constitutes an additional component for performing high-throughput assays: the additional structure of claims 30-31, a support surface, a reagent for use in the assay or something else. As such it is not clear if the structure of claims 30-31 constitute the additional component of claim 29 or are additional structure of the system. For examination purposes, claim 29 will be treated as any additional structure will constitute the additional component: a support surface, a reagent or the structural elements of claims 30-31. Claims 32-34 also have the additional component problems of claims 29-31. It is additionally not clear what constitutes "high-throughput assays or reactions in microtiter plates". Is this a minimum number of assays/reactions performed over a defined time period, a minimum number

Art Unit: 1743

of assays/reactions performed at the same time by the system or some other definition? In other words the phrase "high-throughput assays or reactions in microtiter plates" in claims 29-34 is a relative phrase which renders the claim indefinite. The term "high-throughput assays or reactions in microtiter plates" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-9, 12 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Norris (US 5,592,289). In the patent Norris teaches a self-aligning mechanism for positioning analyte receptacles comprises a loading carriage which bears a tray. In its preferred embodiment, the positioning mechanism of Norris has a loading carriage (200), which carries the tray (244). The loading carriage is slidingly mounted in a structure and includes two guide pins (222,224) situated along the front of the loading carriage, one guide pin (226) located along the side of the loading carriage, and one stop pin (238) positioned at the rear thereof. In the paragraph bridging columns 2-3 Norris teaches that they desire to provide a positioning mechanism for specimens to be assayed by a measuring instrument where the positioning mechanism allows insertion of a receptacle containing the analyte samples to be assayed by

Art Unit: 1743

conventional and inexpensive robotic mechanisms, and provides accurate alignment of the analyte receptacle, e.g., a microplate or a silicon wafer, with respect to the measuring instrument performing the assays (see also column 6, lines 33-39). The device also has a biasing devices or pushers such as a leaf spring (268), helical spring (280), actuators or magnets (paragraph bridging columns 6-7 and column 8 lines 24-54). Since the microtiter plate is not positively recited as an element of the structure, where it is touched by the alignment member(s) has no patentable moment relative to the positively recited structure. Additionally instant paragraph [00042] shows that the point of contact with the microtiter plate is preferably the inner wall but that it is not exclusively required to align the microtiter plate.

8. Claims 1-2, 12-15 and 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Bevirt (US 6,063,579). In the patent Bevirt teaches an alignment mechanism to precisely position a work surface to facilitate the transfer of materials in an automated manner. In column 1, Bevirt teaches that a microtiter plate or other piece of laboratory equipment that is subject to multiple rounds of heating and cooling during a series of manipulations may become nonuniform in the flatness of its working surface causing the depth of individual wells to vary and resulting in problems with automated material transfer from the plate. The invention overcomes the described problem during material transfer processes by providing a method for flattening or elongating the work surface in order to precisely align the work surface in relationship with a dispenser. In figures 4-5 the functioning of the device is taught. As illustrated in figure 4, a plate, such as a 384-well microtiter plate (50), is placed on a mold (52). The figure shows the positioning of the microtiter plate prior to applying pressure. The microtiter plate is shown elevated from the bottom surface (54) of the mold and supported by the top portion (56) of an elastomeric seal (58). An internal structure (60) is used to correctly position the microtiter plate with respect to the structure prior and during the application of a vacuum. The figure also shows a vacuum channel (62) leading from a vacuum port to individual vacuum outlets. Figure 5 illustrates how the plate is deformed to flatten the work surface of the assay plate once pressure is applied. The microtiter plate (70) has a plurality of wells (72), each having a well bottom (74), which may contact the bottom surface (76) of the mold. An internal structure (78) keeps the microtiter plate centrally positioned with respect to the rest of the mold and any material dispenser positioned above the mold structure. Once pressure is applied, the elastomeric seal

Art Unit: 1743

(80) is sufficiently flexible to allow for vertical or horizontal motion of the outer rim (82) of the plate when the plate is compressed against the substantially planar upper surface (84) of the mold. The position of the center region (86) is maintained by the internal structure. Typically, as a consequence of the movement of the plate, the shape of the elastomeric seal has changed. Since the microtiter plate is not positively recited as an element of the structure, where it is touched by the alignment member(s) has no patentable moment relative to the positively recited structure. Additionally instant paragraph [00042] shows that the point of contact with the microtiter plate is preferably the inner wall but that it is not exclusively required to align the microtiter plate.

9. Claims 1-12, 21-23, 29, 39-40 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Burton (WO 99/04228) or Modlin (US 6,071,748). The published application and the Modlin patent have equivalent disclosures that anticipate the above claims. Since both have equivalent disclosures the patent will be described. The anticipatory disclosure in the published application is shown in figures 40-43 and described on pages 46-51. In the patent Modlin describes a high-throughput light detection instrument. Figure 24 shows a general structure in which the light detection instrument is a part. Column 2 lines 56-62 discusses what is typical in current automated high-throughput analyzers including assay analyzers, liquid handling systems, robotics, computers for data management, reagents and assay kits, and microplates for automation of sample dispensing to data collection. In figures 22(a-c) and 23 Modlin teaches a transporter assembly used in the light detection device of the patent. Figures 22a-b show a stage for supporting a composition for analysis by the analyzer in the form of a transporter (600). The transporter includes a transporter body (602) and substantially parallel first and second transporter flanges (604a,b) that extend outward from the transporter body. First and second transporter flanges terminate in first and second transporter extensions (606a,b) that turn in toward one another without contacting one another. The transporter body, flanges, and extensions lie substantially in a plane and define a transporter cavity (608) that is larger than any sample containers that the transporter is intended to support. The shape of this cavity, rectangular, is chosen to accommodate the shape of the preferred sample containers, such as microplates. In the analyzer, long sides of the rectangular sample container are positioned against the flanges. Transporter shelves (610) along portions of the body, the flanges, and the

Art Unit: 1743

extensions form a structure that supports the bottom of the sample container. Other support mechanisms, such as **pins or pegs**, also could be employed instead of or in addition to shelves. The transporter also includes an automatic sample container positioning mechanism (620) for precisely and reproducibly positioning sample containers within the cavity along Y and X axes with positioning arms (622a,b) that contact the sample container to control its Y and X position, respectively. The Y-axis positioning arm (622a) lies substantially within a channel (624) in the body and includes a rod (626a) having the bent shape shown. A first end (628a) of the rod terminates near the cavity with a bumper tab (630a,632) for engaging a sample container. A second end (634a) of the rod terminates away from the cavity in an actuator tab (636a) for controlling movement of the arm. An Y-axis biasing spring (642a) is present. X-axis positioning arm (622b) also lies substantially within the channel (624) in the body and is similar to the Y-axis positioning arm, except that the first end segment (628b) terminates in a lever tab (630b) in the X-axis positioning arm rather than a bumper. The X-axis positioning arm is connected via the lever tab to an X-axis positioning lever (654) that lies along the transporter flange (604b). The X-axis positioning lever includes two functional lever projections (656,658) and is pivotally mounted about a lever pivot axis (659) on the transporter near the intersection of the body and the flange (604b). A first lever projection (656) is substantially perpendicular to the flange (604b) and abuts the lever tab on the X-axis positioning arm for actuating the positioning lever. A second lever projection (658) also is substantially perpendicular to the flange (604b) and includes an edge (660) for contacting a sample container. In use the transporter occupies a loading position substantially outside a housing for a person, robot, or mechanical stacker to place a sample container into the cavity so that the bottom of the sample container rests on the transporter shelves. Under the action of both positioning arms, the sample container is precisely and reproducibly positioned (registered) against a reference corner (672) within the cavity. The biasing springs (642a,b) can be chosen to have different strengths, so that the X-Y positioning action is performed less or more forcefully. As long as the microplate is placed in any position on the lower guide shelves, it can be adjusted into place by the automatic microplate positioning mechanism. A sensor (not shown) detects the presence of the sample container. The transporter can also eject the sample containers. Figure 23 shows a perspective view of the transporter mounted on base platform (700) with drive mechanisms for moving the

Art Unit: 1743

transporter between loading and examination positions. The drive mechanism is provided multiple mechanisms for moving the transporter. Since the microtiter plate is not positively recited as an element of the structure, where it is touched by the alignment member(s) has no patentable moment relative to the positively recited structure. Additionally instant paragraph [00042] shows that the point of contact with the microtiter plate is preferably the inner wall but that it is not exclusively required to align the microtiter plate.

10. Claims 1, 3-5, 12, 29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Lancaster (US 3,568,735). In the patent Lancaster teaches a laboratory microtitration dispensing apparatus. Relative to the instant claims applicant is directed to figures 9-10 and their associated discussion. In the device a carrier plate (40) may support a plurality of separate vials or tubes or may suitably support a transparent microtitration plate (140) having a plurality of wells (142). When the latter is used, the carrier is provided with a titration plate locator and guide assembly as shown in figure 10 including a rectangular plate (144) fixed to the carrier by rivets (146), the upper projecting ends of which serve as locator pins received within the cutout corners (148) of an hollowed locator (150) on which the titration plate rests as shown in figures 5 and 6. The sides of the titration plate overlap the sides of locator with the base of the wells resting on the bottom of locator. This locator assembly enables an operator to readily replace one titration plate for another and ensures that the wells of the titration plate will be accurately aligned with their respective corresponding needles (128) during a dispensing operation. Since the microtiter plate is not positively recited as an element of the structure, where it is touched by the alignment member(s) has no patentable moment relative to the positively recited structure. Additionally instant paragraph [00042] shows that the point of contact with the microtiter plate is preferably the inner wall but that it is not exclusively required to align the microtiter plate.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1743

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
12. Claims 13-15, 17-20, 24, 27-28, 30-35, 37-38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton or Modlin as applied to claims 1-12, 21-23, 29, 39-40 and 42 above, and further in view of Cathcart (US 5,443,791), Markin (US 5,417,922) and Bevirt as explained above. The Burton application and Modlin patent do not teach specifics regarding the structure for liquid handling systems, robotics and reagent, assay kit and microplate storage.

In the patent Cathcart teaches an automated Molecular biology laboratory. In the device a liquid-handling instrument has a worksurface with registration for modular stations to support containers of liquid, pipette apparatus with a pipette tip coupled to a sensing circuit, a robotic translation system for moving the pipette tip, and a control system with an iconic user interface for programming and editing. A gauge block registered on the worksurface provides for calibration using the sensing tip, and register cavities on the worksurface provide for modular stations. There is a wash station for the pipette tip on the worksurface. An automated laboratory based on the liquid-handling system has heating and cooling and a sealable incubation station as well as a magnetic separation station. Methods are disclosed using the apparatus to convey droplets of liquid, to aspirate with minimum tip contamination, to mix liquids in containers, and to validate the worksurface. Procedures in chemistry, particularly in biochemistry, present generally more difficult problems for automation than many other kinds of processes and procedures. One reason is that there is often a very long sequence of steps in a biochemical procedure, such as gene detection and sequencing DNA. Another is that an automatic system needs to be very versatile, because different kinds of starting materials and different analytical purposes require different steps, different order of steps and the use of different kinds of chemical reagents. A third is that sample quantity is, for various reasons, quite limited, and only very small volumes, often on the order of microliters, must be used. What is needed is automatic

Art Unit: 1743

robotic apparatus for doing liquid transfers with very small quantities of liquids, and in a manner that avoids carryover and evaporation. Such an instrument needs to be modular in nature so that container stations may be interchanged, with modular stations for holding containers so that such operations as sample preparation and cleaning may be done off-line. Methods for operation of such apparatus are needed allowing a relatively large number of samples to be processed at a time, with samples and reagents placed in a close array to preserve space. The robotic actions need to be rapid to minimize overall processing time and extremely accurate to be able to access many small sites. Such an apparatus needs to be integrated with a control system that allows an operator to easily and quickly set up procedures with different variables, different step sequences, and different samples and reagents. Also needed is laboratory apparatus based on such a liquid handling system to incorporate further techniques, such as temperature control and a separation station, to be able to fully automate specific chemistry protocols such as for gene detection and DNA sample purification. The general form of the apparatus is shown in figure 1 and for performing DNA sequencing the automated laboratory has a closeable, heated, clamped-lid thermal cycling station (21), an actively cooled enzyme storage station (23), a wash station (25), a reagent storage position (27) for storing and presenting frequently used reagents, a DNA sample stage (28), a wash buffer storage (30), and two magnetic particle wash stations (26,29) for manipulating paramagnetic particles in suspension in liquid mixtures. Also shown is a gauge block (24) for use in calibrating the robotic drives for the apparatus. The various stations are arranged on a worksurface (22). In the preferred embodiment the stations on the worksurface are registered in cavities machined into the worksurface maintaining close tolerance dimensions from cavity to cavity and to the position of the gauge block, so modular stations may be interchanged while maintaining information about the position of containers relative to the worksurface and the gaugeblock.

In the patent Markin teaches a specimen carrier for transporting conventional specimen tubes throughout an automatic laboratory conveyance system includes a generally rectilinear carrier body with a forward face having an identification zone delimited thereon. An identification code is marked in the identification zone so as to permit mechanical sensing and identification of the carrier on a conveyor system. A plurality of holes of various diameters and depths are provided in the top surface of the carrier to receive conventional specimen tubes of

Art Unit: 1743

various types with the top ends of the specimen tubes located at a predetermined height above the top surface of the carrier. A specimen carrier (10) may be temporarily stored on storage racks (70), as shown in figure 6. Each storage rack includes a base plate (72) with a plurality of locator pins (74) projecting upwardly from the upper surface of the base plate. Locator pins are arranged in sets of pairs that are longitudinally spaced apart so as to correspond with a pair of apertures (62,64, see figure 3) on each specimen carrier. Pin pairs are spaced apart laterally a distance such that specimen carriers are laterally spaced apart to permit the specimen carrier to be grasped by the jaws (76) of a robot arm (78).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the various components of Cathcart, Markin and Bevirt into the Burton or Modlin analyzers because of the ability to carry out complex procedures such as the high-throughput procedures of Burton or Modlin in a minimal amount of time as taught by Cathcart.

13. Applicant's arguments filed May 5, 2005 have been fully considered but they are not persuasive. Relative to claims 29 and 32 and the claims that depend therefrom, there are new issues relative to the structure of the additional component being shown in the figures. Furthermore, the definition of what constitutes a high-throughput assay/reaction is not established either in the claims or in the specification and therefore there is no clear way to determine the scope of the additional component. Additionally, due to the open language used in the claims, additional structure is covered as long as the required elements are present. There are additional problems that examiner has noted in the rejections above regarding the completeness of the claims or the recited limitation forming a proper further limitation of the structure.

Relative the anticipation rejections examiner points out that the microtiter plate is not positively recited as an element of the claims thus the "contact an inner wall" language in the claims is not limiting on the structure. Examiner also points out that the same structure can be used to contact an inner wall or an outer wall depending on the placement of the microtiter plate and the presence of an inner wall in the microtiter plate. The instant specification at paragraph [00042] also teaches that contacting an inner wall is preferred but does not limit the alignment contact to the inner wall. Since the claims are not directed to a microtiter plate in combination with the positioning device, the position that the alignment member(s) of the references would contact a microtiter plate do not carry patentable weight. Even if the combination were claimed,

Art Unit: 1743

it is only when the claim requires the microtiter plate to be positioned with the alignment member(s) in contact with an inner wall of the microtiter plate that the teachings of the references do not anticipate the claims in this respect. If both the positioning device elements and microtiter plate and the contact therebetween is not required by positively reciting them in the claims then the capability to provide the contact is all that is required and as long as the structure is capable of providing the contact, the reference does not need to teach the contact to anticipate the claimed structure. Another way of looking at it is a claim directed to the structure without requiring the microtiter plate to be present and in contact with the alignment member(s) in a certain configuration is not limited to that particular configuration and the reference does not need to teach it to anticipate the claimed structure. This is relevant to all of the anticipatory references. Relative to the Bevirt reference and language of claim 14 examiner points out that the language does not require either a microtiter plate as a part of the structure. Since there is no requirement that the microtiter plate be present, there is no structural requirement that the perimeter surface of a microtiter plate be in contact with the lip surface. Thus the argument is not commensurate in scope with the claim. Relative to the Lancaster reference, the microtiter plate is not required for the rejected claims and the above comments are appropriate.

In summary applicant is trying to claim and argue the device in use without requiring all of the elements be present and have the structural configuration when the device is in use. In such cases the arguments are not commensurate in scope with the claims and are therefore not persuasive. Relative to the obviousness rejections applicant is relying on the basis of the anticipation rejections argument without any additional arguments directed to the obviousness of the combination. Thus, since the arguments directed to the anticipation rejections are not persuasive, the arguments directed toward the obviousness rejections are also not persuasive on their face.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner's schedule is variable between the hours of about 6:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

A general phone number for the organization to which this application is assigned is (571) 272-1700. The fax phone number to file official papers for this application or proceeding is (571) 273-8300.

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script, reading "Arlen Soderquist".

July 18, 2005

ARLEN SODERQUIST
PRIMARY EXAMINER